REMARKS

Amendments to the claims have been made to respond to the issues and concerns raised in the Office Action, to clarify aspects in the specification and claims, and to refine claim language. The amendments are believed to be consistent with the disclosure originally filed. The amendments also have been particularly presented to avoid, where applicable, any admission or estoppel, generally, negatively affecting the scope of protection provided by the disclosure and claims of the present application, and also in a manner that avoids prosecution history estoppel, limitation of the scope of equivalences, or the like. Claims 45-51 and 136-137 have been cancelled in this response, and claim 138 has been amended to recite "success levels selected from the group consisting of at least 90%, at least 81%, at least 75%, at least 65%, at least 60%, at least 57%, at least 40%, at least 35%, and at least 30% of a typical unsorted equine artificial insemination dosage".

The Office has raised certain obviousness concerns under 35 U.S.C. § 103 with respect to several combinations of references, wherein Rens is relied upon as teaching high speed sorting. In particular, it is stated that Rens teaches sampling rates of 500 sperm/second and 2000 sperm/second, and that the nozzle of Rens allows for sample rates of up to at least 15,000 sperm/second. However, as discussed in the personal interview, the sampling rates of Rens are not equivalent to the sort rates taught by the instant application. A sample rate refers merely to the number of analysis events each second, whereas a sort rate refers to the actual number of sperm sorted each second. There are less sperm sorted each second than are analyzed because not every analysis event yields a conclusion certain enough to warrant a sort. For example, the analysis of an improperly oriented sperm cell within a flow cytometer may yield an indeterminate conclusion as to its sex, with the result that the sperm cell is discarded rather than sorted into an X or Y population. As stated in Rens at column 4, line 17, "the elliptical nozzle of this invention is capable of orienting in excess of 60% of sperm for sorting." This means that Rens sorts substantially fewer sperm than are analyzed – if only about 60% of the sperm sampled in Rens are properly oriented, the remaining 40% will not be sorted because they will not be in a proper orientation for accurate analysis by the flow cytometer. Moreover, as further discussed in Rens at column 2, lines 4-10, as many as 60%-80% of sampled sperm detected by other

processes are not sorted. Consequently, regardless of the sample rate values discussed by Rens, at best only some figure in excess of 60% of the number of sampled sperm are actually sorted. Further, this 60% value appears to be a best-case figure, and Rens does not discuss the particular parameters required to achieve the same. In fact, Rens does not discuss any specific sort rates achieved at all. Accordingly, the combinations of references relying on Rens cannot support an obviousness concern with respect to the sorting rates recited in the present claims.

Additionally, Rens provides no data on rates of successful fertilization achieved using sperm sorted by its technique. This results in an inability to critically evaluate the suitability of sperm sorted by the Rens technique to effectively accomplish successful artificial insemination. For example, even for a given rate at which Rens may sort sperm, the properties of the resulting sorted sample that bear on effective artificial insemination are not discussed. This leaves open the possibility that an artificial insemination sample produced by the technique of Rens may not be able to achieve the success rates recited by the present claims – Rens simply does not provide sufficient data to make this determination. For example, it is entirely possible that the technique of Rens may perhaps compromise the fertilizing ability of the sperm that it sorts. Note that this concern is particularly acute for the use of equine sperm cells given their delicate nature, an issue addressed in the present invention, as discussed below, but not in Rens, which contains no discussion of equine sperm cells at all. Accordingly, the combination of references relying on Rens cannot support an obviousness concern with respect to the success levels recited in the present claims.

Moreover, the achievement of the success levels in the present claims at the sort rates of the present claims would have been unexpected with respect to the teachings of the references cited by the Office. As discussed in the specification at page 5, lines 8-29, equine sperm cells are particularly delicate and normal flow cytometery sorting techniques accordingly may be unacceptable for equine sperm cells. The specification at page 19, lines 25-29 and page 20, lines 1-11 further describes how high speed operation of a flow cytometer may contribute stresses that may adversely affect sperm cells. Moreover, such high speed sorting is particularly necessary for equine sperm cells given the limited window of time in which artificial insemination may be optimally performed and the high numbers of equine sperm cells as compared to other species

required for successful artificial insemination, as described in the specification at page 2, lines 3-25. Accordingly, as described in the specification at page 20, lines 12-30 and page 21, lines 1-3, the present invention teaches techniques that minimize the stresses associated with high speed flow cytometer sorting of equine sperm cells. With attention to Rens, no teaching is made of using flow cytometery to sort equine sperm, indicating the special considerations for high speed sorting of equine sperm cells have not been taken into account. Moreover, high speed sorting of equine sperm cells was a problem beyond the ordinary skill in the art at the time of the invention, because it would require from the ordinary artisan more inventive effort than merely determining the optimum quantities and volumes for an equine artificial insemination sample – it would require some technique to counteract the detrimental effects of high speed sorting on equine sperm cells, which are precisely the techniques taught by the present invention. Therefore, with respect to the references cited and the ordinary skill in the art, only the present case teaches techniques that for the first time permit high speed flow cytometery to become a viable method to separate sperm in equine applications. Accordingly, while Rens may suggest that it would be desirable to use flow cytometry in an equine context, it does not teach techniques for accomplishing this goal and therefore suggests only that it would be obvious to try. *See In Re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988).

The Office has raised certain obviousness concerns under 35 U.S.C. § 103 with respect to several combinations of references, wherein U.S. Patent No. 6,149,867 is relied upon as teaching high speed sorting. As discussed in the personal interview, immediately upon its availability, the Applicant intends to provide a declaration under 37 C.F.R. § 131 to remove the '867 patent as prior art.

In as much as the present submission addresses issues discussed in the personal interview and is a supplement to the Request for Continued Examination, which was itself timely filed, it is believed that the present submission is presented in a timely manner. Consequently, the Applicant respectfully requests consideration of this First Supplement in conjunction with the Request for Continued Examination filed on October 11, 2005.

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Respectfully submitted,
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